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between said liner and said shell [brings] <u>maintains</u> said ridge in[to] <u>a</u> sealing engagement therebetween.

wherein each of said at least one ridges is an annulus integrally formed on said liner, and said smooth inner sealing surface is sized and spaced to receive and seat all of said at least one ridges, said seal thereby restricting migration of [foreign material] debris [from outside of said shell/liner interface to the interior of the shell/liner interface].

57. (Twice Amended) The [prosthesis] <u>acetabular component</u> of Claim [5] wherein said <u>at least one</u> seal extends annularly around the liner to thereby [prevent foreign matter] <u>restrict debris</u> from passing to the screw holes.

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b 10. (Twice Amended) The [prosthesis] <u>acetabular component</u> of Claim [9] <u>16-</u> I wherein each notch includes a pair of <u>inwardly projecting</u> [protruding] lips to grasp said tabs as they engage.

Remarks

Applicant respectfully requests entry of this amendment in order to place the application in condition for allowance or appeal. Entry of the amendment will not require additional searching by the Examiner. Applicant has canceled claims 1, 4, 5, 8, 9 and 11 to 15. Applicant has added new independent claim 16 and amended claims 2, 3, 6, 7 and 10, which now depend from claim 16.

Applicant has amended the specification to more clearly describe the feature of the smooth inner sealing surface 53 of the shell which originally was shown in greatest detail in Figure 2. Figure 2 clearly shows this surface to be flat and smooth, so the amendment of the

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specification adds no new matter. Smooth is used in this application to indicate an ungrooved surface with no sharp corners. Grooves and corners are used in the prior art to provide an interlocking function. The sealing surface of the present invention deliberately avoids these grooves and corners in the sealing surface because they provide a path for debris migration.

For the Examiner's convenience, Applicant has included with this amendment a copy of color brochure entitled Micro-Seal Total Hip Acetabular System, prepared and published after the filing of the patent application, which illustrates the acetabular component of the present invention. There is a detailed, color photograph on the second page showing the inner surface of the shell, as well as the relationship of that surface to the seal of the liner, (also discussed below).

In preparing the amendments, and in particular when preparing new claim 16, Applicant gave careful consideration to the Examiner's comments. It is believed that new claim 16 is not anticipated or rendered obvious by any of the art of record. The acetabular component of claim 16 provides for an acetabular shell having at least one screw hole therein. The inner portion of the shell includes a smooth inner sealing surface, a feature not taught or suggested by any art of record. Moreover, the acetabular component includes a liner configured to seat in the acetabular shell. The liner has at least one circumferential seal and a separate locking ridge designed to engage an interlock groove formed in the inner surface of the acetabular shell.

The art of record relied on by the Examiner in rejecting the claims appear to include structures that arguably could be an interlocking ridge and groove designed to hold a liner within a shell. However, Applicant's primary sealing structure includes a novel

circumferential inner seal which is <u>separate from</u> the snap-lock ridge and groove structures. Only Applicant's claimed acetabular component includes at least one circumferential seal that is positioned to engage the smooth inner sealing surface of the acetabular shell. This arrangement allows for the sealing arrangement between the shell and liner that prevents migration of debris between the liner and shell and out of the screw hole(s).

The inventor, along with other researchers, have conducted studies to show the effectiveness of various acetabular components in inhibiting particle flow. A copy of their yet unpublished results, Effect of Locking Mechanism on Fluid and Particle Flow Through Modular Acetabular Components, is included with this amendment for the Examiner's review. The tests conclude that Applicant's novel sealing arrangement is effective in preventing penetration of debris beyond the seal (p.10).

The Examiner objected to the specification and rejected claims 4-7 and 15 under 35 U.S.C. §112 in that the specification failed to describe a **relatively flat** surface. As stated above, Applicant has amended the specification to more clearly describe the structure specifically shown in Figure 2. The specification and the original drawings show a tapered, smooth peripheral inner surface 53 of the shell which seats the corresponding tapered circumferential sealing ridges of the liner. Thus, Applicant has amended the specification to point out the tapered smooth inner surface and has also amended the remaining claims to specifically include the smooth surface.

Claim 10 was rejected under 35 U.S.C. §112 in that the Examiner regarded "protruding lips" as indefinite. Claim 10 has been amended to remove the basis for rejection.

Claims 1 - 8, 11, and 13 - 14 were rejected under 35 U.S.C. § 102 (b) as anticipated by, or in the alternative under 35 U.S.C. § 103 as being obvious over Adrey et al. Claims 1 -4, 8 - 11 and 13 - 14 were rejected under 35 U.S.C. § 102 (e) as anticipated, or in the alternative, under 35 U.S.C. § 103 as obvious over Mikhail. Claims 13 - 15 were rejected under 35 U.S.C. § 103 as being unpatentable over Zweymuller in view of Muller. Claims 1, 11 and 12 were rejected under 35 U.S.C. §103 as being unpatentable over Tronzo in view of Muller. As stated above, none of the prior art provides for a shell with a snap lock-liner having a separate circumferential seal engaging a smooth inner sealing surface of the shell to form a debris-restricting seal as provided by new claim 16 and the amended dependent claims. The present invention provides not only for a snap-lock, but also for a separate sealing arrangement. This feature is lacking in any of the cited art. Moreover, the novel arrangement of the circumferential seal against the smooth inner sealing surface allows the debris-resistant sealing arrangement to be maintained as force is applied to the acetabular component. This arrangement is far superior to any other, as shown by the results of the unpublished tests included with this amendment.

For the foregoing reasons it is apparent that the invention, particularly as embodied in new claim 16 is allowable over the art of record. Further, the remaining claims which depend from claim 16 also are allowable. Therefore, Applicant respectfully requests entry of the amendment, reconsideration and allowance of the claims, and passage of the case to issue.

Furthermore, Applicant would appreciate the opportunity to speak to the Examiner by telephone to discuss allowability of the claims.

Respectfully submitted,

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